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EXAMINER	
NGUYEN, TRAN N	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/038,933	COELHO ET AL.	
	Examiner	Art Unit	
	Tran Nguyen	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

This communication is in response to the communication filed 12/07/2007. Pending claim(s): 1-24. Cancelled claim(s): 25-27. Amended claim(s): 1, 11-24.

Response to Amendment

The amendment filed 12/07/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The newly added limitation in claims 1, 11, 16 recites "the request includes an intended purpose of using the health information, wherein ***the intended purpose is to determine one or more of an appropriate of the consent***" (emphasis added.

These newly added limitations appear to constitute new matter. Applicant did not point out, nor was Examiner able to find, any support for these newly added limitations in the specification as originally filed.

To the extent that the specification as originally filed provides support for this limitation, Applicant's specification discloses: "the intended use for the health information is another element that may be considered in determining the appropriateness of the consent" (page 15 paragraph 0048).

According to the specification, the intended use data may be used to determine the appropriateness of the consent; however, the Applicant did not point to nor was

Examiner able to find any support for sending the appropriateness of the consent as part of the request from someone seeking to access patient data.

Applicant is requested to clarify the issues discussed above, to specifically point out support for the newly added limitations in the originally filed specification and claims to the extent possible, and to cancel any new matter in the reply to this Office Action.

Specification

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 USC 112, first paragraph for at least the same rationale as discussed above, and incorporated herein.

Claim Rejections - 35 USC § 112

Claim(s) 1-24 is/are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As per claim(s) 1-24, these claims are rejected for at least the same rationale as discussed above, and incorporated herein.

NOTE: The rejection presented hereinbelow if for Applicant's consideration should Applicant properly traverses the new matter issues discussed above in the response hereto.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 11-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As per claim 11, this claim recites a "system" comprising a "port", a "database", an "engine", and an "interface".

When read in light of the specification and the level of ordinary skill in the art, Examiner, in applying the broadest and most reasonable interpretation, considers software *per se* embodiments to be enveloped within the scope of this claim.

Therefore, this claim is directed towards nonstatutory subject matter. See MPEP 2106.01(I).

All claims dependent thereon, namely claims 12-15, fail to remedy these deficiencies, and are therefore rejected for at least the same rationale above, and incorporated herein.

Additional clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim(s) 1-3, 8, 16-18, 22 is/are rejected under 35 U.S.C. 102(e) as being anticipated by Schoenberg (6463417).

As per claim 1, Schoenberg teaches a method (Title) capable of:

(a) controlling access (reads on "transfer") to a patient's medical record (reads on "health information") (column 2 line 36);

(b) distributing medical records over a network (Abstract);

the method comprising:

(a) receiving, by a database server (reads on "an access server") (Figure 1 label 122) operatively coupled with a network (Figure 1 label 160), a request to access patient medical record (column 5 line 33-36) over an intranet (reads on "an internal network") (column 4 line 27), wherein the request is generated by a wireless device capable of displaying patient medical records (reads on "a portable healthcare device") received over the network (column 4 line 43-46);

(b) providing quick access (reads on "immediately") (column 2 line 18) to the patient records stored in the database (column 5 line 47-48), wherein the server system is capable of:

(i) verifying information entered by the physician to uniquely identify a patient (reads on "if a corresponding consent is stored") (column 6 line 1-7);

(ii) verifying a plurality of security access codes entered by the physician with respect to a plurality of constraints (reads on "whether the consent satisfies requirements for release of the health information") (column 6 line 5-13);

(iii) allowing a physician to request access to at least a portion of a patient record (column 5 line 33-36);

(iv) where the security codes were previously set by the patient (column 4 line 52 to column 5 line 32), wherein the system is capable of protecting patient privacy by providing access to the patient's medical record on a need-to-know basis as determined by the patient with the assistance of a physician (reads on "the consent is provided by an owner of the health information") (column 5 line 50-25, line 2-5);

(v) wherein access is provided on a strict need-to-known basis on a granular level, as discussed in (iv) above (reads on "the consent is based on results provided by a filtering component");

(vi) providing information from the categories in which the received security access codes match the assigned security access codes (reads on "a filtering component") (column 6 line 15-21);

(vii) wherein the request to access information is based on a clinical need to protect patient privacy by withholding medically unnecessary patient data (reads on "the request includes an intended purpose of using the health information, wherein the intended purpose is to determine... an appropriateness of the consent") (column 2 line 7-10);

(viii) wherein the request is a request for a specific a patient record (column 2 line 49-50), wherein the security access codes represent a specific portion of the patient record desired to be viewed by the physician 9column 2 line 63 to column 3 line 19);

(c) displaying information in the categories that the physician is authorized to view (Figure 2 label 226).

As per claim 2, Schoenberg teaches that the physician is able to use a wireless device to access the system (column 4 line 43-46).

As per claim 3, Schoenberg teaches notifying the requestor if there are problems with the security codes (Figure 2 label 222).

As per claim 8, Schoenberg teaches determining if the received security access codes satisfy the requester identification constraints (reads on "the suitability of a corresponding consent") (column 6 line 11-13).

As per the set of claim(s): 16, 17, 18, 22, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 1, 2, 3, 8, respectively, and incorporated herein.

In particular, Schoenberg teaches software capable of performing the recited functionality (column 4 line 8-51). See MPEP 2106.01(I).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 4-5, 19-20 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg in view of Edelson (5737539).

As per claim 4, Schoenberg does not teach storing the health information remotely.

Edelson teaches a transient virtual record (Abstract) capable of being stored across a plurality of data warehouses (Figure 16, column 8 line 20 to column 9 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Edelson within the embodiment of Schoenberg with the motivation of providing data privacy (column 8 line 63 to column 9 line 3).

As per claim 5, Schoenberg teaches using fingerprints (column 5 line 45), retinal scans (column 5 line 44), and security codes (reads on "digital signature data") (column 6 line 1-20) to identify the patient (reads on "comparing the corresponding consent with stored consent data") (column 5 line 37-45).

Insofar as the remainder of the claim is concerned, the applied art need not teach these limitations in view of the optional limitations recited therein.

As per claim 19, Schoenberg teaches re-authenticating the requestor (Figure 2 label 219, 220, 222).

Schoenberg does not teach storing the health information remotely.

Edelson teaches a transient virtual record (Abstract) capable of being stored across a plurality of data warehouses (Figure 16, column 8 line 20 to column 9 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Edelson within the embodiment of Schoenberg with the motivation of providing data privacy (column 8 line 63 to column 9 line 3).

As per the set of claim(s): 20, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 5, respectively, and incorporated herein.

Claim(s) 6, 21 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg in view of Snowden (20020026332) and Edelson.

As per claim 6, Schoenberg does not teach "determining if consent is required".

Snowden teaches accessing anonymous patient data (reads on "determining if consent is required") (page 7 paragraph 0123).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Snowden within the embodiment of

Schoenberg with the motivation of providing economic benefits (Snowden; page 7 paragraph 0122).

Schoenberg and Snowden do not teach storing the health information remotely.

Edelson teaches a transient virtual record (Abstract) capable of being stored across a plurality of data warehouses (Figure 16, column 8 line 20 to column 9 line 3).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of Edelson within the embodiment of Schoenberg and Snowden with the motivation of providing data privacy (column 8 line 63 to column 9 line 3).

As per the set of claim(s): 21, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 6, respectively, and incorporated herein.

Claim(s) 7 is/are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoenberg in view of Applicant Admitted Prior Art (AAPA).

As per claim 7, Schoenberg teaches that the system is capable of being used by any medical care provider requestor (column 2 line 35-39).

Schoenberg does not teach "a pharmacy benefit manager".

AAPA teaches PBM's accessing patient data (Specification; page 3 paragraph 0004).

All component parts are known. The only difference is the combination of "old elements" into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of AAPA within the embodiment of Schoenberg, since the operation of the requestor is in no way dependent on medical record system, and a standard requestor may be used with a record system to achieve the predictable result of accessing the data contained therein.

Claims 9-13, 23-24 are rejected under 35 U.S.C. 102(e) as anticipated by Schoenberg, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schoenberg in view of Official Notice.

As per claims 9-10, Schoenberg teaches Internet communication (Figure 1 label 160).

Schoenberg does not teach "a wrapper for acceptance by a next segment in the network pathway".

Examiner submits that that the Internet is a plurality of interconnected routers, wherein data is routed from a source to a destination based on the TCP/IP protocol, wherein a destination is attached to the data (reads on "a wrapper"). According to the TCP/IP protocol, when a router receives data, the router forwards the data to the next router on the network for delivery to the final destination. At the final destination, the TCP/IP data is dropped, leaving the original data.

Notwithstanding the above, Official Notice is taken of these facts.

All component parts are known. The only difference is the combination of "old elements" into a single embodiment.

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of the Official Notice within the embodiment of Schoenberg, since the operation of the Internet is in no way dependent on the medical record system, and a standard network communication protocol may be used with a network to achieve the predictable result of transferring data between remote computers.

As per the set of claim(s): 11, 12, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 9, 8, respectively, and incorporated herein.

As per claim 13, this claim is rejected for substantially the same rationale as applied to claim 9 above, and incorporated herein.

In particular, Schoenberg teaches using the Internet to route data between the database and the requestor (Figure label 160).

As per the set of claim(s): 23, 24, this set of claim is rejected for substantially the same rationale as applied to the rejection of the set of claim(s): 9, 10, respectively, and incorporated herein.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as obvious over Schoenberg in view of de la Huerga (5903889), or in the alternative, as obvious over Schoenberg in view of Official Notice as applied to parent claim 11 above, and further in view of de la Huerga.

As per claims 14-15, Schoenberg does not teach determining the type of information received and determining an appropriate software application program therefor.

De la Huerga teaches processing patient data based on the data type of the patient data (column 3 line 55-65).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the teachings of de la Huerga within the embodiment of Schoenberg, or in the alternative, Schoenberg and the Official Notice with the motivation of providing interoperability (de la Huerga; column 1 line 53-65).

Response to Arguments

Applicant's arguments with respect to claims 1, 16 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Kessler (20010034618) teaches PBMs working closely with physicians to administer benefits and monitor compliance.

Fenner (5095480) teaches the general state of the art in network communication.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tran (Ken) N. Nguyen whose telephone number is 571-270-1310. The examiner can normally be reached on Monday - Friday, 9:00 am - 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, C. Luke Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. N./
Examiner, Art Unit 3626
03/31/2008

/Robert Morgan/
Primary Examiner, Art Unit 3626